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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,602	07/25/2003	William P. Santamore	08396.0004	9738

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,602	SANTAMORE ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

It is suggested that the headings not be underlined.

2. The disclosure is objected to because of the following informalities: "shortenings" should read "shortening" in paragraph 5, "general" should read "generally" in paragraph 6, and "incorporates" should read "incorporate" in paragraph 42.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In regards to claim 1, "is physically modified" is in the passive voice. This renders the claim vague because it is not a definite method step, but a result of some undefined action. It is suggested to use the active voice to claim a method step, such as, "physically modifying the mechanical properties". The examiner has interpreted the claim as containing this step and the claim should be amended accordingly.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 9, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by McVenes et al. (5,489,294).

8. In regards to claim 1, McVenes et al. disclose a method comprising identifying a target region of myocardium with an intramural space and delivering a lead (14) having an electrode (20) that is connected to a therapeutic or diagnostic device (5) wherein the tissue is physically modified (Fig. 13 and col. 7, line 4). Please note that the examiner is interpreting the cavity produced by the lead as a physical modification and the inclusion of a lead comprised of metal and polymer will inherently alter the mechanical properties of the identified area because the materials have different mechanical properties than heart tissue.

9. In regards to claim 3, the device is a pacemaker (col. 2, line 56).

10. In regards to claim 9, the lead is substantially arcuate (Fig. 2).

11. In regards to claim 11, delivery comprises a guidewire (22). Please note that the examiner is interpreting the needle as a wire that guides the insertion of the lead.

12. In regards to claim 12, the lead comprises echo features (col. 4, line 13). Please note that the examiner is interpreting the interface between the MP35N alloy wires (25)

and the PVF tube (35) as an echo feature because any interface of two materials with different densities will produce an ultrasound signal.

13. In regards to claim 13, the lead comprises radiopaque features (25). Please note that the examiner is interpreting the wires as radiopaque because it is well known in the art that metals, such as MP35N, are not transparent to x-rays.

14. In regards to claim 14, the lead comprises a drug-eluting surface (abstract).

15. Claims 1, 2, and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Zacouto (5,305,745).

16. In regards to claim 1, Zacouto discloses a process involving identifying a target region of myocardium with an intramural space and delivering a lead (6) having an electrode (14) that is connected to a therapeutic or diagnostic device (1) wherein the tissue is physically modified (Fig. 1).

17. In regards to claim 2 and 6, the "systolic performance" and "diastolic performance" are both increased (col. 28, line 49). Please note that the examiner is interpreting an increase in heart rate as an increase in systolic and diastolic performance because the systolic and diastolic periods are performed more frequently.

18. In regards to claims 4 and 5, the device is a defibrillator and a cardiac resynchronization device (col. 28, line 16). A defibrillator is a cardiac resynchronization device because it resynchronizes the depolarizations of the cardiac muscle cells.

19. In regards to claim 7, the targeted area includes an ischemic zone (col. 23, line 22).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claim 8 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zacouto. Zacouto discloses that electro active bridges span cardiac muscle with "important mechanical and/or hemodynamic deficiencies" (col. 24, line 35). Zacouto discloses this feature of his invention as well as an ischemia detection function (col. 23, line 3), inherently providing his invention with the ability to perform the claimed method. Alternatively, it is well known in the art that ischemia is an "important mechanical and/or hemodynamic deficiency". Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the embodiment of Zacouto's invention disclosed in column 24, line

35 to an ischemic area of the heart to correct the progressive stretching of myocardial fibers associated with this condition.

23. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over McVenes et al. in view of Altman (RE 37,463). McVenes discloses the essential features of the claimed invention except for utilizing a stylet to apply the electrode. Altman teaches of utilizing a stylet to apply an intramyocardial electrode to provide the stiffness necessary to push the lead during placement (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify McVenes et al.'s invention by providing a stylet to provide the stiffness necessary to push the lead during placement.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Other examples of intramyocardial electrodes are provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571)272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK

GEORGE R. EVANISKO
PRIMARY EXAMINER
9/2/5